NHS Rotherham

Patient Group Direction (PGD) for

Supply / Administration of Hepatitis B Vaccine (Engerix B®, HBvaxPRO®) to Children aged from birth and adults by Registered Nurses employed or commissioned by NHS Rotherham who have been certified after completing an agreed training plan.

PGD Number:	VI 13
Author:	Kathy Wakefield and Lisa Murray
Date Sent to Non-prescribing Procedure Advisory Group:	13.3.13
Date Ratified at Prescribing Committee:	20.3.13
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Implementation:	Relevant Clinical Lead
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Key Words:	Hepatitis B vaccine, Engerix B®, Engerix B ®, HBVaxPRO®, Patient Group Directions, Vaccinations.
Date Uploaded & By Whom:	

NHS Rotherham

Patient Group Direction No. VI 13

Patient Group Directions are written instructions for the supply or administration of medicines to groups of patients who may not be individually identified before presentation for treatment.

The majority of clinical care should be provided on an individual, patient-specific basis. The supply and administration under a PGD should be reserved for those limited situations where this offers an advantage for patient care (without compromising patient safety), and where it is consistent with appropriate professional relationships and accountability.

- Each PGD has a unique identifier allocated by the Prescribing Adviser responsible for the management of Patient Group Directions for the organisation.
- Once a PGD has been given approval, the date on which the PGD comes into effect will be inserted by the Prescribing Adviser prior to submission onto the NHS Rotherham intranet.
- The PGD must be reviewed within two years of authorisation
- PGDs that have failed to be reviewed and re-ratified ***must not*** be used past their expiry date and patient specific direction (prescriptions) must be used to authorise supply of medicines.

Supply / Administration of Hepatitis B Vaccine (Engerix B®, HBvaxPRO®) to Children aged from birth and adults by Registered Nurses employed or commissioned by NHS Rotherham who have been certified after completing an agreed training plan.

1. Clinical Condition or situation to which the direction applies

Drug Name: Hepatitis B Vaccine (Brands-Engerix B®, HBvaxPRO®).

Clinical Indications	Immunisation of those considered at risk of exposure or following exposure to Hepatitis B virus (HBV)

Criteria for Inclusion	• Valid, legal consent obtained • Age from birth • Babies born to mothers who are positive for hepatitis B surface antigen or to mothers who have had acute hepatitis B during pregnancy. • Intravenous drug users including those who inject intermittently. • Drug users who are likely to "progress" to injecting, for example those who are currently smoking heroin and/or crack cocaine, and heavily dependent amphetamine users. • Children of injecting drug users. • Non injecting drug users who are living with current injectors. • Sexual partners of injecting drug users. • Individuals whose sexual behaviour is likely to put them at risk eg. Men who have sex with men and male and female sex workers. • Close family contacts of a case or individual with chronic hep. B infection. • Haemophiliacs and individuals receiving regular blood transfusions or blood products and carers responsible for the administration of such products. • Residents in residential accommodation for those with severe learning disabilities. • Individuals in day care, schools or centres for those with severe learning disabilities following risk assessment. • Patients with chronic liver disease including milder liver disease such as those who are chronically infected with the hepatitis C virus. • Families adopting children from countries with a high or intermediate prevalence of hepatitis B. • Short term foster carers (and their families) who receive emergency foster placements. • Permanent foster carers (and their families) who accept a child known to be at high risk of hepatitis B.
Criteria for Exclusion	• No valid, legal consent from parent / guardian. • Hypersensitivity to a component of the vaccine. • Previous severe reaction to vaccination. • Severe febrile illness.

	• Healthcare workers including students and trainees who have direct contact with blood or blood-stained body fluids or with patients' tissues. • Occupational Exposure: Employers are required to undertake their own Occupational Health Risk Assessment to determine if immunisation is required through their own occupational health provider. • Post exposure prophylaxis (except babies born to Hep B positive mothers). • Immunisation for travel purposes. **NB** patients with chronic renal failure require a different dose of vaccine and are not covered by this PGD- refer to doctor for a patient specific direction.
Action if Excluded	• If excluded because of lack of consent- Obtain valid, legal consent. • For acute febrile illness advise when vaccine may be given. • Specialist advice must be sought on the vaccine and circumstances under which they should be given. The risk to the individual of not being immunised must be taken into account. • Arrange for further appointment if needed. • Referral to GP / Paediatrician. • Record in patient record. • Notify Child Health for under 19s. • If vaccine required for travel purposes it can be given via a Patient Specific Direction.
Action if Patient declines Treatment	• Advise about the protective effects of the vaccine and the risks of infection and disease complications. • Inform or refer if appropriate to Medical Practitioner or other relevant health professional. • Document action and, if known, reason for refusal and advice given in patients clinical record. • Give general harm/risk reduction advice and document this in clinical record.
Notes for doctors / drug interactions	Minor illnesses without fever or systemic upset are not valid reasons to postpone immunisation. If an individual is acutely unwell, immunisation may be postponed until they have fully recovered. This is to avoid confusing the differential diagnosis of any

	acute illness by wrongly attributing any signs or symptoms to the adverse effects of the vaccine. Individuals with immunosuppression or with HIV infection (regardless of CD4 counts) should be considered for hepatitis-containing vaccines in accordance with the recommendations above. However, these individuals may not develop a full antibody response if they are immunosuppressed, and vaccine protective efficacy has not been studied. Re-immunisation should be considered after treatment is finished and recovery has occurred. Specialist advice may be required. Hepatitis B infection in pregnant women may result in severe disease for the mother and chronic infection of the newborn. Immunisation should not be withheld from a pregnant woman if she is in a high-risk category. There is no evidence of risk from vaccinating pregnant women or those who are breast-feeding with inactivated viral or bacterial vaccines or toxoids (Green Book). Since hepatitis B is an inactivated vaccine, the risks to the foetus are likely to be negligible, and it should be given where there is a definite risk of infection. Drug interactions-none. NB: The licensed vaccines contain different concentrations of antigen per ml, therefore practitioners must ensure that they follow the specific manufacturer's dosage. Vaccination should not be delayed while awaiting test results for Hepatitis B markers.

2. Description of treatment

Drug Name: Hepatitis B Vaccine (Brands-Engerix B®, HBvaxPRO®)

Name, strength and formulation of drug	Hepatitis B vaccine-suspension of hepatitis B surface antigen **Brands:** Engerix B® (20mcg/ml) 1ml pre-filled syringe/1ml vial Engerix B® (paediatric,20mcg/ml) 0.5ml pre-filled syringe/0.5ml vial HBvaxPRO® (10mcg/ml) 0.5ml pre-filled syringe HBvaxPRO® (10mcg/ml) 1ml pre-filled syringe HBvaxPRO® (40mcg/ml) 1ml vial **NB**. The use of **Fendrix®** is not covered by this PGD as it is only indicated for patients with renal

	insufficiency and is not licensed for use in children under 15 years of age.
Legal status	POM
Storage	Vaccines must be stored, transported and disposed according to manufacturers and the Department of Health guidelines and current legislation.
Dose/dose range	See tables at end of PGD.
Method /route	Intramuscular injection in the deltoid region in adults and older children. Anterolateral thigh is the preferred site in neonates, infants and young children. Avoid buttock region as vaccine efficacy is reduced. **Bleeding disorders**-administration must be by deep subcutaneous injection.
Frequency of administration	See tables at end of PGD.
Total dose number	See tables at end of PGD.
Patient/ carer advice and follow- up treatment	• Inform individual about possible side effects and their management. • Give advice on temperature control if they become feverish. • Give advice regarding normal reaction to the injection. • Inform patient when subsequent doses are due when applicable. • Please include a copy of any patient information to be given with this medicine. (Provision of the Package Leaflet is a legal requirement). • Local reactions (pain, erythema, induration and oedema) within 48 hours after vaccination, and persisting for 1-2 days. • Where patient under the age of 19 years, inform Child Health Department that vaccination has been given. **Following immunisation/vaccination:** The patient should be observed for an immediate adverse reaction, usually 5-10 minutes and should remain under observation until they have been seen to be in good health and not to be experiencing an immediate adverse reaction.

3. Records

1. The following records should be kept either paper or computer based
   For all vaccinations, the following information should be entered on all manual records including the Personal Child Health Record (PCHR-red book), computerised records and data collection for Child Health Information Services (CHIS):

   Records should be kept at ..... and information passed to patient and GP.
   - Complete Record of Attendance documentation and if appropriate enter on record 'Protocol fulfilled'
   - Patient's name, address, date of birth and consent given
   - Diagnosis
   - Name of medication
   - Dose given.
   - Brand, Batch Number and Expiry Date (if supplied)
   - Signature & name of staff who administered or supplied the medication, and also, if relevant, signature & name of staff who removed/discontinued the treatment
   - Route and site of administration (record all sites of administration to allow any reactions to be related to the site of the injection
   - Contact details of GP (if registered)
   - Information & advice given to patient (including side effects)
   - Details of any adverse drug reaction and actions taken, including documentation in the patient's medical record. Any adverse reaction must be notified to GP.
   - Referral arrangements (including self care)
   - Date administered / supplied
   - Any serious adverse events that may be attributable to black triangled drugs ▼ should be reported via SUI trust procedure and then to the MHRA using the yellow card system.
2. **Audit Trail Data Collection**

- A record of all individuals receiving treatment under this Patient Group Direction should also be kept for audit purposes within each practice/service.

- **Reconciliation**: Stock balances should be reconcilable with Receipts, Administration, Records and Disposals on a patient-by-patient basis
- **Storage**: Standards must be consistent with the Summary of Product Characteristics. All medication must be stored in a secure locked environment away from the direct patient care area

4. Anaphylaxis - Emergency Treatment

Before administering any medication the possibility of anaphylaxis must be discussed and documented with the patient/carer prior to administration of any medication, which may produce an anaphylactic reaction.
When giving any medication the following should always be readily available:

- Access to the patients notes
- Adrenaline (Epinephrine) 1 in 1000 for intramuscular (i.m.) injection for use in emergency (NB: **check expiry dates** regularly)
- Syringes and needles of **suitable size** and capacity for dose.
- Patient Group Direction for the Administration of Adrenaline (Epinephrine) 1 in 1000.
- Access to a telephone

PLEASE BE AWARE OF RESUSCITATION COUNCIL GUIDELINE.

Adrenaline (Epinephrine) 1 in1000 (1mg/ml)	**For intramuscular injection**	
Age	Dose	Volume
Children under 6 years	150 micrograms	0.15ml
Children 6 – 12 years	300 micrograms	0.3ml
Adults and Child 12-18 years	500 micrograms	0.5ml
These doses may be repeated if necessary at 5-minute intervals according to blood pressure, pulse and respiratory function.		
Special cautions: see BNF 3.4.3	Epinephrine/Adrenaline	

BNF (64th edition) section 3.4.3 page 202-205

(Updated Jan 2008)

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Supply and Administration of Hepatitis B Vaccine for Adults and Adolescents

Name of Vaccine	Engerix B 20mcg/ml		
Type/Induction Course	**Normal**	Accelerated	Very rapid
Age	16 years and over	16 years and over	18 years and over
Dose	1ml	1ml	1ml
Schedule for Primary Course	**0, 1**month, **6** months after 1st dose	**0, 1** month, **2** months, after 1st, **12** months after 1st dose	**0,7** days, **21** days, **12** months after 1st dose
Total Doses to be Given	3	4	4
Additional Information	Single booster 5 years after primary course may be sufficient-see 'Green Book'.		

Name of Vaccine	HBvaxPro	
Strength	10mcg/ml	10mcg/ml
Type/Induction Course	**Normal**	Accelerated
Age	16 years and over	16 years and over
Dose	1ml	1ml
Schedule for Primary Course	**0, 1**month, **6** months after 1st dose	**0, 1** month, **2** months, after 1st, **12** months after 1st dose
Total Doses to be Given	3	4
Additional Information	Single booster 5 years after primary course may be sufficient-see 'Green Book'.	

This document expires on 20.3.15

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Supply / Administration of Hepatitis B Vaccine (Engerix B®, HBvaxPRO®) to Children aged from birth and adults by Registered Nurses employed or commissioned by NHS Rotherham who have been certified after completing an agreed training plan.

Supply and Administration of Hepatitis B Vaccine for Neonates and Children (16 years and over).

Name of Vaccine	**Engerix B**			
Strength	20mcg/ml	20mcg/ml	20mcg/ml	10mcg/ml
Type/Induction Course	**Normal**	Accelerated	Accelerated if low compliance is anticipated	Neonates born to Hep B surface antigen positive mother.
Age	0-15 years	0-15 years	11-15 years	Birth
Dose	0.5ml	0.5ml	1ml	0.5ml
Schedule for Primary Course	**0, 1** month, **6** months after 1st dose	**0, 1** month, **2** months, after 1st, **12** months after 1st dose	**0, 6** months after 1st dose	**0, 1** month, **2** months, after 1st dose, **12** months after 1st dose
Total Doses to be Given	3	4	4	4
Additional Information	Single booster 5 years after primary course may be sufficient-see 'Green Book'.			

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Children aged from birth and adults by Registered Nurses employed or commissioned by NHS Rotherham who have been certified after completing an agreed training plan.

Supply and Administration of Hepatitis B Vaccine for Neonates and Children up to and including 15 years of age).

Name of Vaccine	HBvaxPro		
Strength	10mcg/ml	10mcg/ml	10mcg/ml
Type/Induction Course	Normal	Accelerated	Neonates born to Hep B surface antigen positive mother.
Age	0-15 years	0-15 years	Birth
Dose	0.5ml	0.5ml	0.5ml
Schedule for Primary Course	0, 1month, 6 months after 1st dose	0, 1 month, 2 months, after 1st, 12 months after 1st	0, 1 month, 2 months, after 1st dose, 12 months after 1st dose
Total Doses to be Given	3	4	4
Additional Information	Single booster 5 years after primary course may be sufficient-see 'Green Book'.		

Professional Responsibility All practitioners

- The practitioner will ensure he/she has the relevant training and is competent, including contra-indications. He/she will attend training updates as appropriate. **Details of the competency programme developed for use with this PGD must be attached (see PGD process above).**
- The practitioner will have due regard for the their Professional Conduct and Guidelines for the Administration / Supply of Medicines
- It is the responsibility of the individual practitioner to ensure that he/she has appropriate knowledge of the product prior to proceeding. Refer to the Summary of Product Characteristics (SPC) or current BNF for further details on the product.
- Each individual must have received a personal copy of the PGD and signed on the list of individual professionals who may work within this PGD (kept with master copy of this PGD)
- Must be competent in the recognition and management of anaphylaxis.
- Must have access to all relevant DH advice, including the relevant CMO letters or training and competent in all aspects of immunisation including contraindications and recognition and treatment of anaphylaxis where appropriate.
- Must have access to a current copy of the BNF and *Immunisation against infectious disease* (The 'Green book') and comply with its recommendations (available on DH website – www.dh.gov.uk/greenbook) where appropriate.
- Annual attendance at the NHS Rotherham's or workplace update on resuscitation skills and the management of anaphylaxis within the community.
- Maintenance of own level of updating with evidence of continued professional development (PREP requirements).
- Regular updates in immunisation, vaccination, anaphylaxis and cardiopulmonary resuscitation where appropriate.
- To reinforce and update knowledge and skills in this area of practice, including basic resuscitation and anaphylaxis training, with particular reference to changes and national directives.
- Such practitioners that meet the above criteria for training have NHS Rotherham approval to administer/supply Hepatitis B Vaccine in accordance with this PGD without a doctor's prescription, and with the patient's informed consent.
- Storage and handling of medicines should be carried out accordance with NHS Rotherham's Medicines Policy.
- The EC Labelling and Leaflet Directive 92/27 applies to all supplies of medicine, including those supplied under Patient Group Directions and all products other than those immediately administered must be labelled for supply to patients.

Sources: HSC 200/026 Patient Group Directions; BNF 64th Edition (Sept. 2012); Current Summary of Product Characteristics for product.
Refer to NHS Rotherham Procedure N1 Procedure for Emergency Treatment of Anaphylactic Reactions in the **Community (link http://websrv.rotherhampct.nhs.uk/?FileID=9575) UK Resuscitation Council (January 2008)**

Other reference sources.

5. Management of Patient Group Direction

Developed by:-	Name & Title	Signature	Date
Prepared and approved by: *Name and title in block capitals*			
Lead doctor/dentist			
Consultant in area concerned *Name and title in block capitals*			
Lead pharmacist	*Lisa Murray*	*Lisa Murray* L. Murray	21.3.13
Lead health professional from group who will administer/supply medicine *e.g. Sister XXXX Diabetic Nurse Specialist*			
Strategic lead for Infection Control and Vaccination and Immunisation.	Kathy Wakefield		

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This Patient Group Direction for use in NHS Rotherham is authorised by us			
Job Title	**Name**	**Signed**	**Date**
Director of Public Health	*Dr. John Radford*		
Medical Director	~~*Dr. David Plews*~~ *Joan Daw*		3.4.13
Head of Medicines Management	*Stuart Lakin*		21/3/13
Senior Partner (or delegate) - for GP employed nurses only			

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The ..... named below, being employees or contractee's of

NHS Rotherham based at.....*Clinic

OR GP Employer Name* .....

*delete/complete as appropriate

are authorised to administer/supply .....
as specified under this Patient Group Direction

Register of Staff Trained and Assessed to Administer or Supply this Medicine:
(additional sheets may be attached)

"I confirm that I have read and understood the content of this patient group direction and that I am willing and competent to work under it within my professional code of conduct".

Name of authorised practitioner	Signature of authorised practitioner	Clinical manager or GP	Signature of clinical manager or GP	Date